Appl. No.: 10/538,392 Patent 1951328-00001US

Art Unit: 1641

Reply to Office Action of June 27, 2008

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-26 Canceled

27. (Currently Amended) A system for detecting glycated albumin in a sample and determining the percent glycated albumin comprising:

a single application pad containing a sample well;

a first assay comprising a first test strip that measures measuring glycated albumin in said sample;

a second assay comprising a second test strip that measures measuring total albumin in the same sample as said first assay; and

means for calculating percent glycated albumin,

wherein said first test strip and said second test strip have disposed therein microparticles which specifically being components of said sample.

28. (Currently Amended) The system of claim 27 wherein said first assay measures glycated albumin by the steps of:comprises:

contacting a drop of blood with an anti-glycated albumin antibody-coated microparticle such that glycated albumin present in said blood binds to said antiglycated albumin antibody; and

detecting said bound glycated albumin.

29. (Currently Amended) The system of claim 27 wherein said second assay measures total albumin by the steps of:comprises:

contacting a drop of blood with an anti-albumin antibody-coated microparticle such that albumin present in said blood binds to said anti-albumin antibody; and

detecting said bound albumin.

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30. (Previously Presented) The system of claim 27 wherein said system is an immunochromatographic system.

31. (Currently Amended) The system of claim [[30]]27 wherein said immunochromatographic system for determining the percent glycated albumin in a blood sample comprises:

a first test strip that measures glycated albumin and a second test strip that measures total albumin; and

means for calculating percent glycated albumin comprises a measurement device that reads, calculates and displays the result as the percentage of glycated albumin compared to total albumin in the sample.

32. (Currently Amended) The system of claim [[31]]27, wherein said first test strip has disposed therein is comprised of

microparticles coated with a first antibody to glycated albumin, and an immobilization agent covalently bound to said test strip.

- 33. (Previously Presented) The system of claim 32 wherein said immobilization agent is an antibody to glycated albumin.
- 34. (Previously Presented) The system of claim 32 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.
- 35. (Currently Amended) The system of claim [[31]]27 wherein said second test strip has disposed therein is comprised of

microparticles coated with a first antibody to albumin, and a second antibody to albumin covalently bound to said test strip.

- 36. (Previously Presented) The system of claim 35 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.
- 37. (Currently Amended) The system of either of claims 34 or 36, wherein said microparticles may be are colored or tagged with a fluorescent compound.

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38. (Currently Amended) The system of claim [[31]]27 wherein the first test strip and the second test strip may be are arranged in a configuration selected from the group consisting of parallel, or opposite to each other, or and at an angle to each other.

- 39. (Currently Amended) The system of claim [[31]]27 wherein the first test strip and the second test strip are enclosed in a rigid cassette.
- 40. (Previously Presented) The system of claim 31 wherein said measurement device is a reflectance spectrometer or a fluorometer comprising:

a detector for measuring the glycated albumin test result;

a detector for measuring the glycated albumin control band;

a detector for measuring the total albumin test result;

a detector for measuring the total albumin control band;

an internal computer chip for measurement and calculation;

a liquid crystal display;

an external port to transfer data to an external computer and/or printer;

a battery and/or an external power source; and

a rigid external case with an aperture for inserting the test cassette.

- 41. (Previously Presented) The system of claim 40 whereby the one or more than one test result can by displayed on said measurement device's liquid crystal display in numerical format or in graphical format.
- 42. (Previously Presented) The system of claim 40 further comprising an internal memory chip capable of storing one or more than one test result.
- 43. (Previously Presented) The system of claim 42 whereby the one or more than one test result can be transferred to an external computer or printer.
- 44. (Currently Amended) A method of monitoring glycated albumin using a point-of-care assay and determining a percent glycated albumin level comprising:

depositing a drop of blood into a single sample well of an immunochromatography system test cassette;

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transferring said blood into the sample application pad thereby allowing blood plasma to pass into a first conjugate pad of a first test strip and into a second conjugate pad of a second test strip;

binding said blood plasma to anti-glycated albumin antibody-coated microparticles in said first conjugate pad;

binding said blood plasma to anti-total albumin antibody-coated microparticles in said second first conjugate pad;

allowing blood plasma-bound antibody-coated microparticles <u>in each of</u> said first test strip and said second test strip to individually to-migrate across said conjugate pads to a-fixed bands of membrane-bound antibody;

binding said blood plasma-bound antibody-coated microparticles <u>in each</u> of said first test strip and said second test strip to said membrane bound antibody[[y]]<u>ies</u> to form <u>a visible colored or fluorescent bands</u>;

inserting said immunochromatography system test cassette into a measurement device;

providing numerical results of glycated albumin levels from said first test strip and total albumin levels from said second test strip; and calculating said percent glycated albumin.